SEP 2 8 2000

K001833

Summary for Special 510K #001833

13 July 00

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, Maryland 20850
Attn: Dr. John Chen
FAX 301 480 4224

1. **510(k) Application Date** 6/13/00

2. **Contact Name** Lee Myers, MD or Andrew Jones

3. **Establishment** Northwest Medical Physics Equipment, Inc
   Address 21031 67th Ave W, Lynnwood, WA 98036
   Phone (425) 672-2841
   Fax (425) 672-8470

4. **Est. Reg. No.** 3025265
   Operator No. 9002478
   Est. type manufacturer (M)

5. **510(k) Reason** modification to incorporate standard frame-based immobilization technology into **K904908** for increased rigidity of patient head fixation

6. **Indication for use** " Where patient head fixation is required for radiosurgery procedures the titanium frame is intended to provide fixed, rigid patient immobilization during such procedures."

7. **Brief description** **NMPE** is herewith submitting the incorporation of standard, stereotactic frame-based immobilization technology. This provision increases the level of patient head fixation without otherwise altering the treatment planning or treatment delivery methodology. In particular, the distinctive, three-point, implanted fiducial localization technique, completely separate and unrelated to the stereotactic frame technology, remains unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2000

Lee Myers, M.D.
Director of Operations
Northwest Medical Physics Equipment, Inc.
21031 67th Avenue West
Lynnwood, WA 98036

Re: K001833
pReference Treatment System
Dated: September 12, 2000
Received: September 13, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Dr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

6. Indications for Use enclosure

Page_____ of_____

510 (k) Number (if known):___(device modification)_____

Device Name:_____Stereotactic Irradiation System

Indications For Use:

The indications for use are such intracranial diseases as gliomas, neuromas, meningiomas, astroctyomas, arteriovenous malformations, and metastatic carcinomas.

The software is used to electronically import CT images containing the target to be irradiated, to determine the precise location of the ~~the~~ target with respect to implanted fiducials, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.

(PLEASE DO NOT WRITE BELOW THIS LINE - ~~CONTINUE ON ANOTHER~~ PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001833